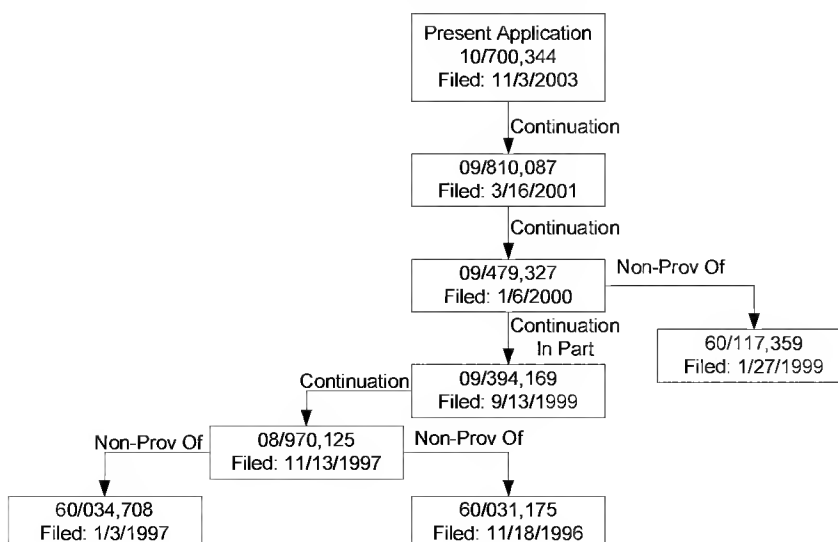


## **REMARKS**

Applicants appreciate the examiner's review of the prior art and request reconsideration of the pending claims in view of the following remarks. Applicants have added new claims 111-113. Support for the new claims may be found at, among other places, page 2, lines 8-18; page 5 lines 9-12; page 5, lines 15-20; and figures 1-6 and 10-18 of the originally filed application. Applicants previously added claims 93-110, cancelled claims 1-36, 38, 39, 48, 50-62, 64, and 74-92, and amended claims 37, 63, 93, and 102. Accordingly, claims 37, 40-47, 49, 63, 65-73, and 93-113 are currently pending in the application.

## **Priority**

The Office Action suggests that the present application is not entitled to the benefit of provisional applications 60/031,175 and 60/034,708 because application 09/479,327 (from which the present application claims priority) was not filed within one year of the provisional applications. However, the present application and the 09/479,327 application also claim priority from U.S. Application number 09/394,169 which, in turn, claims priority from 08/970,125. The 08/970,125 application was filed within one year of the above mentioned provisional applications. The priority of the present application is shown in the flowchart below. Please note that the flowchart has changed slightly from the version filed in the response dated August 17, 2009 to correct minor errors in the prior version and more clearly show the priority chain.



The advisory action of August 25, 2009 suggests that the priority information does not appear in the first paragraph of the specification as originally filed and, therefore, the priority claim is improper. Applicants respectfully disagree and would like to direct the examiner's attention of page 1, lines 5-22 of the application as filed. Additionally, as mentioned above, Applicants have amended the priority statement to better clarify the priority claim and the relationships between the applications to which the present application claims priority.

Therefore, it is clear from the above that the present application claims priority back to U.S. patent application serial number 08/970,125 which was filed within 1 year of U.S. provisional applications 60/031,175 and 60/034,708. Accordingly, the present application is entitled to a priority date of November 18, 1996 (the filing date of U.S. Provisional Application 60/031,175).

### **35 U.S.C. 102(a) Rejections**

The office action rejects claims 37, 40-47, 49, 63, 65-73, 93-110 under 35 USC 102(a) as being anticipated by WO 98/22178 (Cote, hereinafter "Cote").

As mentioned above, the present application correctly claims priority to U.S. Provisional Applications 60/034,708 and 60/031,175 which have filing dates of January 3, 1997 and November 18, 1996, respectively. Therefore, the present application has a priority date of November 18, 1996 and Cote, which also claims priority from U.S. Provisional Applications 60/031,175 and 60/034,708, is not prior art. Accordingly, Applicants believe that this rejection is moot.

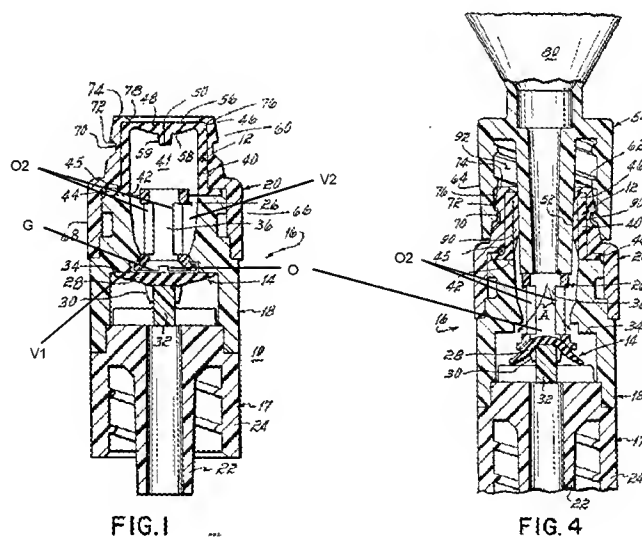
### **35 U.S.C. 103(a) Rejections**

The office action rejects claims 37, 40-47, 49, 63, 65-73, 93-110 under 35 USC 103(a) as being unpatentable over U.S. Patent No. 5,578,059 (Patzner, hereinafter "Patzner" in view of U.S. Patent No. 5,190,067 (Paradis et al., hereinafter "Paradis").

Claim 37 defines, in relevant part, a medical valve having a housing, a plug member, and a substantially flexible, resilient gland member secured to the housing and the plug member. The plug member is a cannula, defines a channel for directing fluid through the valve, and has an

opening nearer to its distal end. The gland member normally occludes the opening and contacts the distal section of the plug member (e.g., the portion of the plug member distal to the opening).

Patzer fails to teach such a valve. Rather, Patzer teaches an anti-reflux valve with an environmental barrier. In particular, Patzer's valve has a series of connected housings (e.g., actuator housing 18, tapered thread housing 20, etc.), an actuator 26 and a disc valve 14. Patzer's disc valve 14 includes a resilient disc 28 and an underside skirt 30 that connects to a nipple 32 on the housing (i.e., luer lock connector 17). In operation, a taper 52 of a male luer 54 impacts against actuator 26 moving it downwardly into disc 28, causing the disc 28 to deform over the nipple 32 and open the valve (col. 4, lines 45-55, Fig. 4). As discussed in Applicants' response to the office action dated February 11, 2009 and as mentioned in the office action dated June 16, 2009, Patzer has a gap between the disc valve 14 and the actuator 26 (see Figures 1 and 4 reproduced below) and does not teach or suggest a resilient member that is secured to both a housing and a plug member.

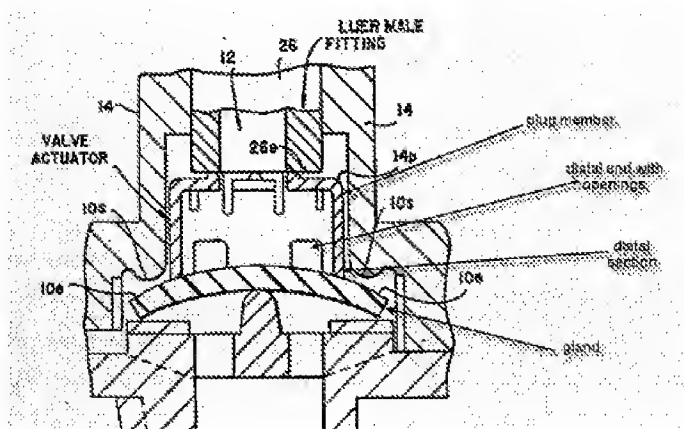


Additionally, Patzer also fails to teach or suggest a resilient gland member that normally occludes an opening within a plug member that is nearer to the plug's distal end. The Office Action suggests that Patzer's disc valve 14 constitutes the resilient member and Patzer's actuator 26 constitutes the plug member. The office action (and the office action dated February 11, 2009) also suggests that channel 36 extends through the actuator 26 such that actuator 26 has an opening (marked as O on the reproduced figure above) at the bottom (i.e., because the disc 14

deforms into the opening). However, even if this were true, Patzer's disc valve 14 does not normally occlude the opening. As known in the art, and as described in our responses dated December 12, 2008, August 19, 2008, and May 8, 2009, the term "occlude" means to close, or obstruct. Nothing in Patzer is closing or obstructing the channel 36 or opening O. Rather, as discussed above, the disc valve 14 is spaced from the bottom of the actuator 26 such that a gap (G in the reproduced Figures) is created between the disc valve 14 and actuator 26. This gap prevents the disc valve 28 from normally occluding the opening O and allows fluid and/or particulates to enter and exit the internal area of the actuator 26 from the volume between the actuator 26 and the disc valve 14 (e.g., volume V1 in the reproduced figures), and the volume surrounding the actuator 26 (e.g., volume V2 in the reproduced figure).

Applicants would also like to note that the openings (e.g., openings O2 in the figures reproduced above) on the sides of Patzer's actuator 14 are also not normally occluded by a gland member. These openings are clearly open and unoccluded in both the closed and open modes of the valve (see figs 1 and 4 reproduced above). Therefore, fluid and/or particulates may enter and exit the internal area of the actuator 26 from the volume surrounding the actuator 26 (e.g., volume V2 in the reproduced figure).

Moreover, Paradis also fails to teach the deficiencies of Patzer. In particular, as shown in reproduced Figure 1B below, Paradis teaches a direction flow control device that has a diaphragm 10e, pre-biasing prongs 10p, and a plunger 14p (see Figure 1B as shown in the office action dated June 16, 2009 and reproduced below). In operation, as a luer male fitting is inserted into Paradis' control device, the plunger 14p moves downward causing the diaphragm 10e to move away from its seat 10s (i.e., become unseated). When the plunger 14p is moved upwards (e.g., when the luer is removed), the diaphragm reseats against seat 10s. When seated, the pre-biasing prongs apply a small force against the diaphragm 10e to properly seat the diaphragm 10e. (e.g., see Figure 1B reproduced below and column 6, lines 35-52). Nowhere does Paradis teach or suggest a resilient member that that is secured to both a housing and plug member.



The office action suggests that Paradis' plunger 14p constitutes a moveable plug and Paradis' diaphragm 10e constitutes the resilient member. The office action also suggests that there is no gap between the diaphragm 10e and the plunger 14p. Although Paradis mentions that the diaphragm is "held in position against" the plunger (column 8, line 16) and there does not appear to be a gap between them, Paradis does not teach or suggest that the diaphragm is secured to the plunger 14p, as required by claim 37. As known in the art, the term secured means attached and/or fastened. Additionally, dictionary.com defines secure as "to make firm or fast, as by attaching" (<http://dictionary.reference.com>) and the American Heritage Dictionary defines secure as "to make firm or tight; fasten" (<http://education.yahoo.com/reference/dictionary>). Paradis's diaphragm is not attached and/or fastened – at best it is simply in contact with or held against the plunger.

The office action appears to confuse contacting or being held against with being secured to. As the terms suggest, contacting or being "held against" merely requires contact between the diaphragm 10e and the plunger 14p. As mentioned above, the phrase "secured to" requires more – being attached/fastened in some manner – which Paradis does not teach or suggest. Applicants would also like to point out that Applicants' discussion of the gap between Patzer's disc valve 14 and actuator 26 (e.g., above and within Applicants' response to the office action dated February 11, 2009) was to point out that the disc valve 14 was not secured to the actuator 26 (e.g., if there is a gap between the components, the disc valve 14 cannot be secured to the actuator 26), not that the claim merely requires contact. Therefore, Patzer and Paradis fail to teach or suggest, alone or

in combination a resilient member that is *secured to* both a housing and a plug member, as required by claim 37.

Additionally, like Patzer, Paradis also fails to teach or suggest a resilient gland member that normally occludes an opening within a plug member that is nearer to the plug's distal end. Rather, like Patzer's side openings O2, the openings within Paradis' plunger 14p are open and unoccluded in both the open and closed modes (see figures 1B and 2A) and, because the diaphragm 10e is merely a flat member, the diaphragm is unable to occlude the opening. Therefore, fluid and particulates are free to enter and exit the internal area of the plunger 14p from the volume between the plunger 14p and the diaphragm 10e and the volume surrounding the plunger 14p. Neither reference, thus, teaches a gland member that normally occludes an opening within a plug member.

Accordingly, claim 37 is allowable over the combination of Patzer and Paradis. Moreover, claims 40-47, 49, and new claims 111-113 which depend from claim 37 are allowable for at least the same reasons. Additionally, dependent claims 40-47, 49, and new claims 111-113 are also allowable over the combination of Patzer and Paradis for the additional limitations set forth therein. For example, claim 111 requires that the gland member be attached to the housing and the plug member. As discussed above, there is a gap between Patzer's disc valve 14 and actuator 25 and Paradis' diaphragm 10e is merely held against the plunger 14p. Therefore, neither reference teaches a resilient member that is attached to a plug member. Additionally, claim 112 requires that a portion of the gland member circumscribe at least a portion of the plug member. As shown in Figure 1 of Patzer and 1B of Paradis, no part of Patzer's disc valve 14 circumscribes a portion of the actuator 26 and no part of Paradis' diaphragm 10e circumscribes a portion of Paradis' plunger 14p. Furthermore, claim 113 requires that the opening in the plug member allow fluid flow through the plug member when the valve is in an open mode. Therefore, even if Patzer's opening O (e.g., as relied upon by the office action) is normally occluded (e.g., in the closed mode) by Patzer's disc valve 14 (see Figure 1 reproduced above) (which as discussed above is not), the opening does not allow fluid flow through the valve when the valve is in the open mode. Rather, as shown in Figure 4 (also reproduced above), Patzer's disc valve 14 blocks this opening when the valve is open and fluid only passes through the side openings O2.

In a manner similar to claims 37, claims 63, 93, and 102 also define medical valves having resilient gland members that are secured to a housing and a plug member and that normally occlude an opening in the plug member. Accordingly, claims 63, 93, and 102 are allowable over Patzer for the same reasons as discussed above with regard to claim 37. Moreover, claims 65-73, 94-101, and 103-110 which depend from claims 63, 93, and 102, are also allowable for at least the same reasons.

All pending claims therefore are allowable over the cited art. The application therefore is in condition for allowance and such action is earnestly solicited. Applicants believe that a one month extension of time is required and requests that the corresponding fee be charged to deposit account number 19-4972. Additionally, please charge any additional fees required by this paper or credit any overpayment to Deposit Account No. 19-4972. Applicants also request that the examiner contact applicant's attorney, Jonathan C. Lovely, if it will assist in processing this application through issuance.

Respectfully submitted,

/Jonathan C. Lovely, Reg. #60,821/  
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